



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Handwritten signature/initials

In re patent application of
Henryk LUBON et al.

Serial No. 07/943,246

Group Art Unit: 1804

Filed: September 10, 1992

Examiner: D. Crouch

For: EXPRESSION OF ACTIVE HUMAN
PROTEIN C IN MAMMARY TISSUE
OF TRANSGENIC ANIMALS USING
A LONG WAP PROMOTER

REQUEST FOR RECONSIDERATION
OF THE RESPONSE OF JANUARY 24, 1994
FILED UNDER 37 C.F.R. § 1.111

*To Exmr
10/19/94
ECW*

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

The communication is submitted in partial response to the Office Action of May 27, 1994 ("the May action"). For the reasons set forth below, applicants submit that the action did not reflect due consideration of the response filed on January 24, 1994 ("the January response"). Issuance of a new action, based on reconsideration and reexamination of the application in light of the duly considered response is requested.

(1) The May action does not reflect due consideration of evidence submitted to show public availability of materials subject to the deposit requirement

The explanation for the deposit requirement in the action and applicants' comment in the response and in the office action seem to go past one another. To determine the basis for this aspect of the prosecution, applicants have consulted the applicable statutes, rules and sections

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of the MPEP and reconsidered the record on this point. The following comments summarize the statutory and procedural basis for applicants' traverse of the deposit requirement and the reasons applicants believe that the traverse was not given due consideration in the action.

First, the basis for requiring deposit seems to be in dispute, as least in part. Applicants have maintained that the requirement is made on enablement grounds, while the action states that it is on enablement grounds in some places and on written description grounds in other places. There are important differences between the two grounds under Section 112 and the difference in viewpoint therefore deserves discussion. The following comments set out the PTO guidelines in this regard and hopefully will clarify the basis for applicants' previous comments traversing the rejection.

The Federal Rules governing requirements for deposit of biological material are set out in 37 CFR §§1.801-1.809. The rules are augmented by Patent Office procedural guidelines set out in MPEP §§2403-2411. The MPEP sections indicate that a deposit of biological material may be required if: (1) the material is necessary to practice a claimed invention, and (2) those of skill would require undue experimentation to practice the claimed invention if the biological material is not made available to the public through a qualified deposit.

MPEP §2411.01 states that requirements for deposit should be effectuated by an appropriate rejection under Section 112 "clearly indicat[ing] ... the statutory basis" for the rejection and the "reasons" for concluding that the deposit is necessary. The section enumerates the following five statutory bases for rejection to require a deposit.

(1) 35 U.S.C. 112, first paragraph - lack of an enabling disclosure without access to a specific biological material. This ground of rejection should be accompanied by evidence of scientific reasoning to support the conclusion that a person skilled in the art could not make or use the invention defined in and commensurate with the claims without access to the specific biological material.

(2) 35 U.S.C. 112, first paragraph - description requirement. This ground of rejection typically arises in the context that the application as filed does not contain a description to support an amendment

(3) 35 U.S.C. 112, first paragraph - best mode requirement. ... [On] a finding by the examiner that ... the inventor(s) concealed the best mode.

(4) 35 U.S.C. 112, second paragraph - indefiniteness. [On grounds that] the terms in the claims and/or scope of the [claimed] invention are unclear because of an incomplete or inaccurate description

(5) 35 U.S.C. 112, second paragraph - ... [On] evidence, not contained in the application ... that the claims do not set forth what applicants regard as their invention.

(MPEP §2411.01. Emphasis added.)

In the present case, the deposit requirement was made under Section 112, first paragraph and, therefore, it was not on the statutory basis set out in MPEP §2411.01 - (4) and (5).

The rejection also did not allege concealment and, therefore, it was not made on the best mode basis set out in MPEP §2411.01 - (3).

MPEP §2411.01 - (2) provides for a deposit requirement on grounds of inadequate written description. The provision states that the rejection "typically arises" when the written description does not "support an amendment." Since the rejection here does not involve an amendment it would be unusual for it to be based on MPEP §2411.01 - (2).

However, in referring to the deposit requirement on page five of the action, the examiner stated that, "[t]he written description rejection" was made because the application (paraphrasing): (A) discloses only one DNA encoding a polypeptide with protein C activity; (B) does not disclose methods to determine other DNAs encoding a such polypeptides, and (C) the claimed DNAs are defined only by the activity of the protein C polypeptide.

Without contesting the merits of these statements, solely for the purposes of this request, they do not constitute a proper basis for requiring a deposit on grounds of an inadequate description under 35 U.S.C. §112, first paragraph. In fact, in the next sentence, the action itself concludes that "Thus, the deposit requirement was rightfully stated to be need[ed] for the enablement of the claims as the scope limitation set forth."¹ This conclusion is consistent with other statements in the action that the deposit is necessary to insure public availability of DNAs, not because the specification is inadequate in describing the claimed invention. Thus, for the most part, the action itself agrees with applicants' view that the deposit is required for enablement. Furthermore, the DNAs subject to deposit are described as claimed. The reasons set out above do

¹

Emphasis added.

not lead to a conclusion that the description is inadequate, particularly not in a way that would require a deposit. The specification therefore meets the requirements of Section 112 in this respect.

Rather, as the action itself states, the reasons for deposit all pertain to enablement issues. Indeed, as set out below, the action explains that the deposit is required because an individual, who provided a DNA used to make illustrative plasmids of the examples, cannot guarantee public availability of allegedly necessary materials. Adequacy of the written description is judged by whether it describes the subject matter of the claims, exclusive of whether the specification is enabling. The basis for the deposit requirement relates to a starting material that is not claimed, which the examiner believes must be publicly available to practice the claimed invention. Thus, it appears to applicants that the action alleges not that a public source is necessary to describe the claimed invention but that it is necessary for enablement. The deposit requirement therefore does not seem to fit the statutory basis set out in MPEP §2411.01 - (2).

The action very clearly states that the deposit is necessary to make and use the claimed invention, however. And this statement seems unambiguously to fit the statutory basis set out in MPEP §2411.01 - (1): that the specification would not be enabling, "without access to [the] specific biological material" sought to be deposited. Thus, applicants concluded, explained and now reiterate their conclusion that enablement is the only basis for requiring deposit consistent with the statutes and rules that is set out in the examiner's explanations.

Therefore, applicants have traversed the rejection as relating to enablement.

With enablement issues in mind, applicants traversed the requirement on the basis of MPEP §2404.01, which specifically provides that even when access to "specific biological material" is necessary to practice the claimed invention, an applicant need not make a deposit of the material if it is "known and readily available to the public." That is, "No deposit is required ... where the required biological materials can be obtained from publicly available material with only routine experimentation"

Applicants traversed the deposit requirement, under MPEP §2404.01, on grounds that the claimed invention can be practiced using well known and readily available materials. As a preamble in this regard, applicants pointed out that the application generically and by specific examples discloses DNAs for practicing the claimed invention. In particular, applicants pointed out that the specification cites published, readily available references that teach the DNA sequences of such DNAs. Applicants also pointed out that the disclosure describes general methods for manipulating these DNAs for use in the claimed invention and, by way of illustration, also describes the making of two particular constructs in lab bench-level detail. Applicants argued that the disclosure thus is enabling for the DNAs, without a deposit.

Having thus argued, applicants also provided additional evidence that readily available materials are sufficient to practice the claimed invention. In this regard, applicants submitted six references, including U.S. patents, that describe sequences and expression of DNAs which applicants maintain can be used to make DNAs

the same as those sought to be deposited. Applicants argued that the documents illustrated the well known and readily available DNAs and techniques available for practicing this aspect of the claimed invention, which obviate the need for deposit.

It is respectfully submitted that the documents were not given due consideration as evidence that materials for practicing the claimed invention are well known and readily available. Rather, of the arguments and the documents, the action states that: (1) "A source for protein C has not been provided in the specification;" (2) "A listing of potential sources in applicant's response does not provided a listing of sources in the specification as filed," and (3) "In this regard, applicant has failed to make a correlation between the plasmid of the specification and the sequence of the art or applicant's listed sources." Applicants submit that these statements do not reflect due consideration of the point addressed by the remarks and the evidence in the May response.

As to (1), even if "A source for protein C has not been provided in the specification," a deposit requirement would not be necessary if such sources are well known and readily available. Statement (1) does not address applicants arguments that such sources, in fact, are well known and readily available.²

The statement that, (2) "A listing of potential sources in applicant's response does not provided a listing of sources in the specification as filed," also does not address the point supported by the evidence. The

² Furthermore, applicants maintain that the statement does not accurately reflect the information the specification would impart to those of skill in this regard.

"listing of sources," i.e., the documentary evidence submitted in the response, was submitted to show public availability of starting materials sufficient to practice the claimed invention. It was not offered to augment the disclosure.³

Finally, the statement that, (3) "In this regard, applicant has failed to make a correlation between the plasmid of the specification and the sequence of the art or applicant's listed sources" does not take cognizance of the content of the submitted documents, which show that DNAs of the type disclosed in the specification i.e., the same as applicant obtained from the sources mentioned in the specification, are commonly cloned, manipulated and expressed.

The contention that only applicants' DNAs can be used in the claimed invention (if this is the examiner's point) directly contradicts applicants' statement in the specification. As a matter of law and PTO procedure, therefore, the examiner must accept applicants' statement or rebut it by scientifically valid reasoning. Absent such scientifically cognizable reasoning, the rejection is an irrefutable (and improper) presumption that the DNAs used by the inventors are somehow different from other DNAs in a way that neither the inventors nor anyone of skill in the art suspects or understands.

Indeed, the inventors have not discerned something different about any DNAs they used in the illustrative examples that distinguish them from DNAs that could be obtained independently. Those of skill would not doubt

³ Applicants note that well known facts need not be set out in the specification. In addition, applicants maintain that the specification will enable those of skill to obtain DNAs for use in the claimed invention, as set out in the previous response.

the objective truth of applicants statements that DNAs constructed from independently obtained starting material in the manner set out in the specification would be identical to all intents and purposes as the DNAs used by applicant. Indeed, the cloning and characterization of DNAs is fundamental to all of molecular biology and biotechnology is founded on the reproducibility of DNA isolation techniques. A cloned human gene, for instance, β -globin, presumably represents all such human genes. If not, its sequence and function would tell us nothing of interest about human genes. Unless the examiner sets out valid scientific reasons to believe that the genes of applicants' claimed invention can be obtained only from the deposited material, there is no valid basis to assert that only applicants' DNAs will work in this regard. Applicants' evidence of availability also underscores this point, since it shows that DNAs of the type described in the specification have been made and used for expression *in vitro* with results that belie any assertion that the illustrative DNAs in the present application were made from the starting materials that are unique in this regard.

Accordingly, it is respectfully requested that the comments and evidence be reconsidered in this light and a new action be issued accordingly.

(2) Dr. Velander's Declaration under Rule 132 should be entered and duly considered: the original declaration is entered in the identified parent application and is in possession of the PTO, and it is asserted a true copy by the agents' signature in the May response

It is respectfully submitted that the refusal to consider Dr. Velander's declaration was improper. The action incorrectly states that "[T]he information in the

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Velander declaration ... in not of record in this application and cannot be considered." To the contrary, the remarks and the copy in the response clearly placed the declaration in the record and it should have been considered.

The remarks in the response clearly state that the declaration is part of the record in an application for U.S. patent. The identity of that application is indicated clearly in the remarks and in the declaration. Indeed, the examiner points out the originating application in the action. The response clearly represents the copy to be true to the original. And the response is signed by a registered patent agent who is of record not only in the present application but also in the originating application.

Thus, the original declaration has been accepted by and is in the possession of the Patent Office. The originating application is clearly identified and known to the examiner. A copy of the signed original has been submitted in this application. The copy was submitted over the signature of an agent which, by its nature, is an attestation that the copy is a true and unaltered representation of the original, to the best knowledge of the agent.

Accordingly, the declaration should be entered on the record, the May response should be reconsidered giving full weight to the declaration evidence and a new action should be issued, based on the reconsideration.

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For the foregoing reasons applicants request the May response be reconsidered and a new action be issued in which evidence of availability is viewed for its probative value under MPEP §2404.01, and Dr. Velander's Rule 132 declaration is entered and officially considered on the record of this application.

September 13, 1994
Date



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